REMARKS

Claims 61 and 67-84 were pending in the application. Claims 82-84 were withdrawn from consideration. Claims 68 and 73 have been cancelled without prejudice to presentation in future related applications. Claims 61, 74 and 81 have been amended.

Claims 61, 74 and 81 have been amended to further clarify the claimed invention. Support for the amendments can be found throughout the application as originally filed, including, for example, in now cancelled claim 68 and paragraphs [0012], [0013], [0027], [0031], [0065], [0079], [0176], [0177], [0193], [0260], [0290] and Table 113. Paragraph numbering is as set forth in U. S. Published Patent Application US 2006-0194265 A1.

No new matter has been added.

Upon entry of this amendment, claims 61, 67, 69-72 and 74-81 will be pending.

Rejection Under 35 U.S.C. §112, first paragraph – written description

Claims 61 and 67-81 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Office alleges that no support could be found for the acronym "CR1" in the specification and that Table 113, referenced by Applicants in their last response, did not appear "to be of record in the specification". Accordingly, the Office asserts that the term "CR1" represents new matter. Applicants do not agree.

Preliminarily, Applicants note that claim 81 does not include the acronym "CR1" and, accordingly, should not properly be included in the present rejection.

Applicants direct the Office's attention to Table 29 of U.S. Ser. No. 10/322,696 ("the '696 application"), filed December 17, 2002, from which the present application claims priority. On page 46 of the published patent application (US 2004-0166490 A1) of the '696 application, the protein designated as "hP10-030" is described as "complement receptor type 1- related". Applicants respectfully assert that one of skill in the art would readily appreciate that the acronym for complement receptor type 1 is "CR1".

Applicants further note that Table 113 of the present application describes SEQ ID NO:1320 and its related sequences as "complement receptor type 1 – related." Applicants attach hereto a printed copy of Table 113 but note that as set forth on the stamped, return postcard received from the Patent and Trademark Office and on the transmittal filed with the application (copy of each attached hereto), Table 113 was received by the Office and should be of record.

Notwithstanding the foregoing and solely in an attempt to further the prosecution of the pending claims to allowance, Applicants have revised the claim set to include the complete name "complement receptor type 1" with the acronym "CR1".

Accordingly, Applicants respectfully request withdrawal of the new matter rejection under 35 U.S.C. §112, first paragraph.

Claims 61 and 67-81 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Office alleges that the "written description is not commensurate in scope with these method claims drawn to a method of detection of mRNA sequences 98% and 95% sequence identical to SEQ ID NO:1329 ....". Applicants do not agree as such sequence variants and their use in the diagnosis of cancer are clearly set forth in the specification as being in the possession of Applicants at the time of filing.

Preliminarily, Applicants note that claims 61-72 and 76-80 do not recite 95% or 98% sequence identity to SEQ ID NO:1320. Notwithstanding, in an attempt to advance the prosecution of the pending claims to allowance, Applicants have amended claim 61 to recite that the CR1 gene expresses a mRNA comprising SEQ ID NO:1320, or a full complement thereof. Applicants have also revised the claim set to remove reference to sequences having 95% or 98% sequence identity of SEQ ID NO:1320.

In view of the foregoing, Applicants respectfully request withdrawal of the written description rejection under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §102

Claims 61, 67-72 and 80 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Salomon et al. (Endocrine-Related Cancer 7: 199-226, 2000; hereinafter the "Salomon

reference"). The Office asserts that Salomon discloses "methods of detection and subsequent diagnosing of increased human cripto (CR-1) in human colon carcinoma, breast carcinoma and other cancers ..." Applicants do not agree.

Applicants respectfully point out that complement receptor type 1 (of the present invention) and cripto (of the Salomon reference) are distinct genes. As discussed above, the claims have been revised to further clarify the identity of the gene referred to as CR1 by adding "complement receptor type 1". Because Solomon does not disclose or even suggest methods for diagnosing cancer by detecting evidence of differential expression of complement receptor type 1 or by comparing levels of expression products comprising SEQ ID NO:1320 (complement receptor type 1 expression product), Solomon does not anticipate the pending claims.

Applicants respectfully request the withdrawal of the 35 U.S.C. §102 rejection based on the Solomon reference.

Claims 61, 67, 68, 71, 72, 75, 76 and 80 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Guc et al. (Eur. J. Haematol 64(1):3-9, January 2000). The Office alleges that the Guc reference discloses that "surface expression of complement receptor 1 (CR1) was lower in acute myeloblastic leukemia (AML) in comparison to their normal counterparts .... [and that] CR1 mRNA expression was significantly lower in acute lymphoblastic leukemia (ALL) than in the control group ...". Applicants do not agree.

As discussed above, claim 61 was amended to recite methods for diagnosing lymphoma, carcinoma, breast cancer or colon cancer. Claims 67, 68, 71, 72, 75, 76 and 80 depend from amended claim 61. As set forth in the Office Action, Guc discloses relative expression levels of CR1 in leukemias (acute myeloblastic leukemia and acute lymphoblastic leukemia). However, because Guc fails to teach or suggest methods for diagnosing lymphoma, carcinoma, breast cancer or colon cancer based on expression levels of CR1, Guc does not anticipate the claims.

Applicants respectfully request the withdrawal of the 35 U.S.C. §102 rejection based on the Guc reference.

Claims 61, 67-76, 80 and 81 80 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent 6,569,662 ("the Tang patent"). The Office alleges that the Tang patent "discloses a complement [Sequence 259] of SEQ ID NO:1320 ... identified as a polynucleotide that encodes *Homo sapiens* CR1 precursor protein." The Office further asserts that the Tang patent "discloses detection of the presence or amount of polynucleotides or polypeptides in a sample for the diagnosis of metastatic cancer, acute and chronic leukemia, breast cancers and colon cancer." Applicants do not agree.

Applicants attach hereto an alignment between SEQ ID NO:1320 of the present invention and SEQ 259 of the Tang patent. Based on the alignment, it is clear that the disclosure of SEQ 259 in the Tang patent fails to teach or suggest a method for diagnosing lymphoma, carcinoma, breast cancer and colon cancer comprising detecting evidence of differential expression of complement receptor type 1 (CR1) gene in a patient sample, wherein the CR1 gene expresses a mRNA comprising SEQ ID NO:1320 or a full complement thereof. Further, it is evident that the Tang patent fails to teach or suggest a method of diagnosing lymphoma, leukemia, carcinoma, breast cancer or colon cancer comprising comparing the *levels of an expression product comprising SEQ ID NO:1320*, or a full complement thereof, or comparing *levels of a gene which expresses SEQ ID NO:1320*, in a patient sample to a normal control.

Applicants respectfully request the withdrawal of the 35 U.S.C. §102 rejection based on the Tang patent.

Conclusion

The examination of the pending claims and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (302) 778-8458 to clarify any unresolved issues raised by this response.

Applicants do not believe a fee is due for the filing of this response. If Applicants are incorrect, please charge Deposit Account No. 06-1050 the fee and apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 20366-066001.

Respectfully submitted,

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Attachments: paper copy of Table 113 (109 pages)
Copy of stamped, return postcard
Copy of transmittal filed with application
Sequence Alignment – Tang patent SEQ 259 vs. SEQ ID NO:1320